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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARTIN GLEAVE, et al.

Appeal 2007-4460
Application 10/646,436
Technology Center 1600

Oral Hearing Held: April 9, 2008

Before DEMETRA J. MILLS, ERIC B. GRIMES, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANTS:

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The above-entitled matter came on for hearing on Wednesday, April 9, 2008, commencing at 9:25 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Paula Lowery, Notary Registration No. 162073, Notary Public.

THE CLERK: Good morning. This is Appeal Number 2007-4460. The attorney is Ms. Marina Larson.

MS. LARSON: I apologize for my lateness. I spent an exciting half hour in the tunnel between Arlington Cemetery and the Pentagon.

JUDGE MILLS: That happens around here.

We are familiar with your case, and you have 20 minutes.

MS. LARSON: I'm back on my favorite topic of biotech patent attorneys are our own worst enemies. When it comes to enablement or anticipation, it seems that we are running a lot into a double standard of we do sweeping disclosures to try to get to written description for something in our own applications.

We may not succeed at that, but it surely is coming back to bite us when it comes to anticipation rejections. This is one of those cases.

The prior art in this case doesn't disclose anything within the scope of our claim. It has a boilerplate definition for the word "Oligonucleotide," which says it could mean this, this, this and this, and one of those "this" is what we're finding.

We have multiple examples. We don't have an enablement issue. We don't have a written description issue. We have only anticipation based on this would be a good target and, oh, you could make all kinds of different things to do it.

Whether or not written description is reciprocal, that is, you need the same kind of written description to make an anticipation rejection, I think the Elan case, which is cited in the brief, makes it clear that enablement is reciprocal because the Federal Circuit in that case cites --

JUDGE FREDMAN: So your argument is it would not be

enabled to take DNA of 85 percent inhibition, convert that to RNA -- put it into a cell, to expect the clusterin inhibited expression?

MS. LARSON: We don't know for sure if it'll work because the mechanisms are sufficiently different that when we're dealing with RNA molecules, that we don't know.

JUDGE FREDMAN: Really.

MS. LARSON: Standard DNA-type antisense oligos and, for example, siRNA work by totally different mechanisms.

JUDGE FREDMAN: But we're talking about translations. We're talking about a hybridized -- we're doing in-vitro transcription, and we throw in a complementary molecule you're hoping it would inhibit.

MS. LARSON: Normally when we talk about RNA inhibitors, we're talking about the catalytically inhibitory rather than the straight antisense mechanism. It's not clear what they're talking about.

JUDGE GRIMES: Well, the title of their patent is Antisense.

MS. LARSON: That's right, but antisense normally is DNA. They also talk about aptamers, ribozymes and --

JUDGE GRIMES: Is there any reason to think an RNA oligonucleotide would hybridize differently than a DNA? RNA and DNA hybridize by the same method, don't they?

MS. LARSON: Well, at the same basic base pairing, yes.

JUDGE FREDMAN: In effect, does RNA not hybridize more strongly than DNA? When RNA and DNA hybridize, it is, in fact, a stronger hybridization than a DNA.

MS. LARSON: Yes. The thing is, we've never -- none of these issues were ever explored at the prosecution level. We need some direction

-- if these issues should be explored, we are very much in the case of the Elan case that there are lots of things that could be tested here. They said, Go out and play.

I would also comment, by the way, we're particularly offended by this because the patent this is based on comes from a company -- my client went to them. He said, Make us some stuff for this target. Here are our sequences. They went out and patented everything else that we couldn't get because we couldn't make them.

JUDGE FREDMAN: I'm not sure that's relevant.

MS. LARSON: I understand, but, you know, that's what's happening in the industry. I think it is relevant if you're looking at the question of how much weight should a prior art document have.

If you're telling me that it's perfectly obvious that it is enabling, why is it that I am getting an enablement and written description rejection when I try to use those as examples to get a claim? Because I'm getting that.

JUDGE GRIMES: I think the problem we're having with your position is there's case law out there that says a patent disclosure is presumed to be enabling, whether or not it's claimed. We don't have any evidence coming back from you to overcome that.

MS. LARSON: Why should a patent -- no, a patent claim is presumed to be enabled. A patent disclosure cannot be presumed to be enabling for everything it discloses because we don't do what Europe does and make us cut it down to match the claim when it issues. That would be totally wrong.

JUDGE GRIMES: That is what the case law says.

MS. LARSON: No, the case law says the patent has to be

presumed to be valid. That means that the subject matter that ends up being claimed has to be presumed to be enabled. But if the case law says that everything in there, no matter how sloppily disclosed or drafted is enabled --

JUDGE GRIMES: Could I give you the case that says that?

MS. LARSON: Sure.

JUDGE GRIMES: It's Amgen v. Hoechst, 314 F.3d 1313 at 1355. It says, a presumption arises that both the claimed and unclaimed disclosures in prior art patents are enabled. That's what it says.

JUDGE FREDMAN: On a separate point, it's pretty clear from the claim of Monia that RNA is within the scope of the claim. It's broadly claimed -- it lists them, "which inhibits the expression of human clusterin" but doesn't distinguish what the background is.

MS. LARSON: But that doesn't make it --

JUDGE FREDMAN: When we look at the choices for backgrounds, there is a limited set of choices. There's DNA, there's RNA, there's phosphorothioate -- there's not an unlimited number of possible backgrounds.

MS. LARSON: And we don't know within the scope of that -- there's no enablement which of those sequences and which targets within those sequences are, in fact, going to work --

JUDGE FREDMAN: Those are particular -- there were 20 that were shown to work. Monia shows every single one of those.

MS. LARSON: But not as RNA.

JUDGE FREDMAN: Not as RNA, but in the in-vitro system, which is the narrowest your claim encompasses, in the in-vitro system, why would you not expect RNA to work? You have no evidence that it wouldn't

work, and the expectation is --

MS. LARSON: But we're talking about anticipation, we're not talking about obviousness. There was never an obviousness rejection made. If you tell me you want to remand it and say this is not anticipatory, you can't stretch it that far, we'll go in and test those sequences and see if they work as RNA, but I can't ask my client to do things that the examiner is not even required to look at. Because it's not an obviousness rejection, it's an anticipation rejection.

He never made the argument that you're making, ever. It's very hard for an attorney sitting in the prosecution world to respond to arguments that are not made because they have no weight, but they surely do shoot you in the foot later on.

They don't matter at all to the examiner. He said, I don't have to pay any attention to that this is an anticipation rejection, but if somehow you overcome that, now all of those things are there in the record and you have to deal with them later when you're trying to enforce them.

So really the examiner needs -- if this is the argument we need to respond to, then this is an argument that should be made on the record. Not the argument that the examiner made, which was just that this is hugely generic disclosure; look, they define it as including RNA --

JUDGE FREDMAN: You said that.

MS. LARSON: -- which they did. No question. I'd be willing to bet that if I went in and searched those words in that law firm, I would find them in every single patent they have filed.

JUDGE FREDMAN: I don't understand why that matters.

MS. LARSON: Because the importance of what is supposed to

make a difference -- why do we have anticipation and obviousness if you don't take anything back from the prior art?

Well, if this turns up as boilerplate in every single application, to what extent does it put anything into the hands of the art?

JUDGE FREDMAN: I think you'd almost have to say it puts more in the prior art. If everyone knows in a hundred different patents every single time, antisense can be made out of RNA, it seems to me that's more anticipatory. It suggests it even more.

MS. LARSON: I think actually it makes it useless because I've actually received applications from people where there are definitions where the terms that are defined are not used elsewhere in the specification.

I think it takes away because it simply becomes part of the background noise. It's not a specific disclosure of anything.

A person skilled in the art doesn't look at that as an addition to their knowledge. They see it as, in the words of the case we now can't use, an invitation to experiments. Things I might do in the future.

What does that disclosure add to -- if I had said --

JUDGE FREDMAN: If your point is it doesn't add, it seems to me it almost says it's more anticipatory. If it's so well known to the ordinary skill that it doesn't add anything, that they know this, that it's there --

MS. LARSON: If that definition weren't there, you would have looked at this and you would have said, Okay, look here -- you know, then you would make the argument that you've made that why would they not work the same?

It would be obvious to use RNA instead of DNA, and we would put in evidence and we would have an argument based upon the real facts

rather than this definition of paramount significance.

Really what it says -- it's an invitation to go further. The reality is there is no teaching here of RNA beyond saying, Well, we'd like to claim RNA and all these other things, too, but we can't be too specific because you'll get us on written description, so we'll hide it in the definitions.

If I tried to claim an RNA molecule based on this disclosure, specifically, the examiner would reject it on written description.

JUDGE FREDMAN: If they can claim one, as it is in Monia, that an RNA compound -- you think it would be reflected in their description?

MS. LARSON: Absolutely.

JUDGE FREDMAN: Well, I'm not sure that's true, but whatever --

MS. LARSON: At least four out of five times. I'm not going to give perfect consistency because it's not, but at least four out of five times that claim would have been rejected for lack of written description. Probably also for lack of enablement.

That creates a real problem. If it's not enabling for these people, why should it be enabling to hurt me? Yet I see this same rejection that this disclosure --

JUDGE FREDMAN: I guess one of the issues, if it was not enabling, the examiner should have written a scope of enablement rejection, which was not written, in that case.

Claim 1 encompasses RNA expressly. No scope of enablement apparently was written, or if it was, it was withdrawn because the claim issued. It's pretty clear that, in fact, the examiner in at least this reference,

he decided against you, did not say, it's – for RNA – not enabled. The examiner didn't write the enablement rejection.

MS. LARSON: All I can say is four out of five times, you put the words "RNA" in there, you would have gotten an enablement rejection.

JUDGE FREDMAN: We have one case and lots of speculation.

JUDGE MILLS: I believe we understand your point.

Any other comments?

MS. LARSON: Again, I apologize for being late.

(Whereupon, the proceedings at 9:40 a.m. were concluded.)